

### REMARKS

Reconsideration of the present application is respectfully requested.

As regards the objection to the drawings, the lumen outlet arrangement is depicted by numeral 20 in Fig. 2, which is more clear in the accompanying formal drawings.

New claims 14 and 15 constitute original claims 4 and 6, respectively, written in independent form. Since claims 4 and 6 were held to be patentable, it is submitted that claims 14 and 15 are also patentable.

The present invention relates to a retrograde cannula for delivering cardioplegia to a vessel of a heart. The cannula body includes an infusion lumen 16 for conducting the cardioplegia to a lumen outlet 20. An automatically inflatable balloon 12 is provided, and arranged via passage 30, to be inflated by the cardioplegia that is being conducted through the infusion lumen. In order to keep the balloon in an inflated state when the delivery of cardioplegia is halted a valve is provided, e.g., the slidable valve 34 of Figs. 1 and 2, or the flexible sleeve 50 of Figs. 3 and 4, which can be moved from an open position to a closed position in which the passage 30 is closed. Thus, the balloon, and with it the cannula, is held in place in the patient's body even when no cardioplegia is being administered. Hence, there is no need to reinsert or reposition the cannula in order to administer a second dose of cardioplegia.

Claims 1 and 5 stand rejected over Fig. 8 of Briscoe, who discloses a stylet 46 that is inserted into a catheter to stiffen the catheter for entry into a patient's body. The stylet 46 includes a plug 70 at its distal end which prevents a backflow of fluid into the catheter from a patient's body as the catheter is being inserted (i.e., premature inflation of the balloon is prevented). After the catheter has been inserted, the stylet is removed (see column 4, last four lines).

It will be appreciated that the balloon of Briscoe is not adapted to be fixed in place when the flow of cardioplegia is halted. Briscoe's stylet 46 is only intended to be present during initial insertion of the catheter. Thereafter, the catheter is

removed to enable cardioplegia to be administered. When the flow of cardioplegia is halted, the balloon collapses, contrary to the present invention.

An inherent structural difference between Briscoe and the present invention is that Briscoe's plug blocks communication between the lumen inlet and the lumen outlet while it is in position closing the balloon passages. That is best shown in Briscoe's Fig. 20 embodiment. Even though Briscoe's stylet 46 is functioning as a valve to close the balloon passages 190, 192, it is also blocking communication between the lumen inlet and outlet. That is of no consequence in Briscoe because the stylet is only present when inserting the catheter. However, in the presently claimed invention, it is important that the lumen inlet communicate with the lumen outlet while the valve is open and closed.

That difference is now expressed in each of claims 1 and 5 and is neither disclosed by, nor suggested by, Briscoe.

New independent claims 16 and 17 correspond to original claims 1 and 5, respectively, but further recite that the valve (claim 16) or the passage opening and closing means (claim 17) is arranged "externally of the infusion lumen". That is directly contrary to Briscoe's device wherein the stylet is to be inserted into the infusion lumen.

Accordingly, it is submitted that claims 1, 5, 16 and 17 are allowable. Since those claims are generic to both species of the invention, i.e., Figs. 1-2 and Figs. 3-4, it is submitted that dependent claims to both of those species should be allowed. Thus, it is requested that all of claims 1-6 be allowed along with claims 14-17.

Claims 7-13 have been canceled, but Applicant reserves the right to file a divisional application directed thereto.

In light of the foregoing, it is submitted that the present application is in condition for allowance.

Respectfully submitted,

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Attachment to Amendment dated April 14, 2003  
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1. (Amended) A retrograde cannula for delivering fluid to a patient's vessel, the cannula comprising:

a body including proximal and distal ends and an infusion lumen extending therebetween for conducting pressurized fluid from a lumen inlet to a lumen outlet arrangement disposed adjacent the distal end;

an automatically inflatable balloon extending around the body adjacent to, and spaced from, the lumen outlet arrangement, the balloon receivable in the vessel in a deflated state and being inflatable into sealing contact with a wall of the vessel, the body including a passage arrangement for fluidly communicating the balloon with the infusion lumen to enable the balloon to be inflated by the pressurized fluid conducted through the infusion lumen; and

a valve arranged in the body for being shifted between an open position to open the passage arrangement, and a closed position for closing the passage arrangement to keep the balloon in its inflated state when the delivery of pressurized fluid is halted, the valve arranged to maintain fluid communication between the lumen inlet and the lumen outlet arrangement while in its open position and its closed position.

5. (Amended) A retrograde cannula for delivering cardioplegia to a vessel of a heart, the cannula comprising:

a body including proximal and distal ends and an infusion lumen extending therebetween for conducting cardioplegia from a lumen inlet to a lumen outlet arrangement disposed adjacent the distal end;

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an automatically inflatable balloon extending around the body adjacent to, and spaced from, the lumen outlet arrangement, the balloon receivable in the vessel in a deflated state and being inflatable into sealing contact with a wall of the vessel, the body including a passage arrangement for fluidly communicating the balloon with the infusion lumen to enable the balloon to be inflated by the pressurized cardioplegia conducted through the infusion lumen; and

passage opening and closing means for opening the passage arrangement to communicate the balloon with the infusion lumen, and for closing the passage to keep the balloon in its inflated state when the delivery of cardioplegia is halted, the passage opening and closing means arranged to maintain fluid communication between the lumen inlet to the lumen outlet arrangement while in its passage-opening position and its passage-closing position.